16th May 2013

Important Product Information: CoaguChek XS instrument – 'Error 6'

Dear

Roche are writing to you because our records show you have purchased a CoaguChek® XS instrument to monitor your INR.

As you know, the CoaguChek® XS measures your INR up to a value of 8.0. It is known that, in very rare situations, INR values greater than 8.0 can occur – for example if you are undergoing antibiotic treatment or chemotherapy. The CoaguChek® XS detects these very high values and displays the following two messages for your protection:

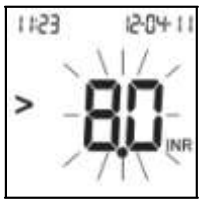

Fig. 1

or

Fig. 2

In both cases, the user manual advises you to consult your healthcare professional immediately.

In April 2013, we were made aware of one case in Norway in which antibiotic treatment resulted in a patient having an INR value greater than 10. However, the CoaguChek® XS instrument returned the following display:

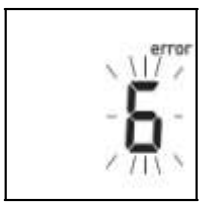

Fig. 3

The user manual tells you that an error has occurred in the measurement process. Although a very high INR value is practically excluded as a reason for this error message, we have decided – as a

precautionary measure – to inform our CoaguChek® XS users about the correct procedure to follow if an "error 6" message is displayed (Fig. 3).

What do I have to do if my CoaguChek® XS instrument displays "error 6"?

If this happens, the most likely cause is that an error has occurred in the measurement process. Please turn off the CoaguChek® XS instrument, remove the test strip and repeat the measurement with a new test strip. Make sure that you do not squeeze your finger while taking the blood and that you do not touch the test strip during the measurement – these are the two most frequent causes of the "error 6" message.

If you follow the correct procedure and "error 6" is displayed again, you should immediately consult your healthcare professional to have your INR checked.

Please be reassured

The CoaguChek® XS instrument continues to effectively measure your INR values – even if you are receiving antibiotic treatment or chemotherapy.

99.99% of the cases in which an "error 6" message is displayed result from an incorrect measurement process. Since the CoaguChek® XS instrument was introduced in 2006, the Norwegian case is the only case anywhere in the world in which an INR value greater than 10 has produced an "error 6".

As product quality is of utmost importance to us, please rest assured that we have thoroughly investigated this technical detail and are amending our product literature to reflect this issue.

To ensure comprehensive communication, we have also informed our healthcare professional customers.

We thank you for your understanding and do apologise for any inconvenience that this may cause. Should you want to ask any additional questions and/or seek clarification please do contact our CoaguChek careline free on 0808 100 7666 (UK) 1800 509 586 (Republic of Ireland), Monday to Friday 09.00 to 18.00.

Yours sincerely,

Roche Diagnostics